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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,776

Applicant(s)

LEE ET AL.

Examiner

Karen E. Toth

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 10, 13-16, 39-42, 44-46 and 48-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 9, 11, 12, 17-24, 26-38, 43, 47, 52-59 and 61-76 is/are rejected.
- 7) ☒ Claim(s) 25 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/7/07, 3/3/05, 2/16/05, 7/19/04.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species 5, A, I, and i in the reply filed on 10 July 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 4-7, 10, 13-16, 39-42, 44-46, and 48-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 July 2007.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 8, 9, 11, 12, 20-22, 27-38, 43, 47, 53-57, 63, and 65-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho (US Patent 6641542).

Regarding claims 1-3 and 8, Cho discloses a method for classifying disordered breathing in a patient comprising detecting a sleep disordered breathing event (column 8, lines 46-48; step 410), sensing motion associated with respiratory effort during the event (column 6, lines 52-54, column 7, lines 19-32, 47-49, and 63-65; step 420), and classifying the event based on the sensed motion (column 6, lines 57-65; column 9, lines 16-19; step 430), where the detection, sensing, and classification are all performed implantably (figures 1 and 2; column 3, lines 14-21).

Regarding claim 9, Cho further discloses using respiration patterns to identify disordered breathing events (column 7, lines 33-46).

Regarding claims 11 and 12, Cho further discloses using transthoracic impedance to detect the disordered breathing (column 7, lines 19-32), which is representative of respiratory system conditions.

Regarding claims 20-22 and 26, Cho further discloses identifying and distinguishing between central, obstructive, and mixed disordered breathing (column 6, lines 57-65; column 9, lines 16-19).

Regarding claim 27, Cho further discloses storing information associated with the disordered breathing event (column 8, lines 39-41).

Regarding claim 28, Cho further discloses transmitting information associated with the disordered breathing event (column 4, lines 62-66; column 8, lines 44-45).

Regarding claim 29, Cho further discloses displaying information associated with the disordered breathing event (column 5, lines 46-49).

Regarding claim 30, Cho further discloses using the event's classification to evaluate disordered breathing trends (column 8, lines 52-60).

Regarding claim 31, Cho further discloses delivering therapy to treat disordered breathing based on the classification of the disordered breathing event (step 440).

Regarding claim 32, Cho further discloses modifying a therapy delivered to a patient based on the classification of the disordered breathing event (column 10, lines 14-16).

Regarding claim 33, Cho further discloses the modified therapy being a disordered breathing therapy (column 10, lines 14-22).

Regarding claims 34-37, Cho discloses a system for classifying disordered breathing comprising a detector configured to detect a disordered breathing event (elements 210, 510-2), a motion sensor configured to sense motion associated with respiratory effort during the event (element 520), and a disordered breathing classification processor coupled to the motion sensor and breathing event detector configured to classify the event based on the respiratory event motion (column 5, lines 57-60), where the detector, sensor, and processor may all be configured to be implantable (figures 1, 2).

Regarding claims 38 and 43, Cho further discloses using a transthoracic impedance sensor to sense respiration and respiratory system conditions (element 510-2).

Regarding claim 47, Cho further discloses that the motion sensor may be an accelerometer (column 7, lines 48-49).

Regarding claims 54-57, Cho further discloses the system being configured to identify and distinguish between central, obstructive, and mixed apneas (column 6, lines 57-65; column 9, lines 16-19).

Regarding claim 63, Cho further discloses the system being coupled to a cardiac rhythm management device (column 4, lines 59-62).

Regarding claim 65, Cho further discloses the system being coupled to a patient management system (column 6, lines 16-29).

Regarding claim 66, Cho further discloses a memory coupled to the processor and configured to store information about the disordered breathing event (column 8, lines 39-41).

Regarding claim 67, Cho further discloses a display device coupled to the processor and configured to display information about the disordered breathing event (column 5, lines 46-49).

Regarding claims 68 and 69, Cho further discloses a therapy unit coupled to the processor and configured to deliver or modify therapy to the patient to treat disordered breathing (column 5, lines 16-20; column 10, lines 1-22).

Regarding claim 70, Cho discloses a disordered breathing classification system comprising means for detecting a disordered breathing event (elements 210, 510-2), means for sensing motion associated with respiratory effort during the event (element 520), and means for classifying the disordered breathing event based on the sensed motion (column 5, lines 57-60), where at least part of the system is implantable (figures 1 and 2).

Regarding claim 71, Cho further discloses means for storing information associated with the event (column 8, lines 39-41).

Regarding claim 72, Cho further discloses means for transmitting information associated with the event (column 4, lines 62-66; column 8, lines 44-45).

Regarding claim 73, Cho further discloses means for displaying information associated with the event (column 5, lines 46-49).

Regarding claim 74, Cho further discloses using the event's classification to evaluate disordered breathing event trends (column 8, lines 52-60).

Regarding claims 75 and 76, Cho further discloses means for delivering and/or modifying a therapy delivered to the patient based on the classification of the disordered breathing event (column 5, lines 16-20; column 10, lines 1-22).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Burnes (US Patent Application Publication 2003/0195571) and Brydon (US Patent 6547743).

Regarding claims 17 and 18, Cho discloses all the elements of the claimed invention, as disclosed above, except for the respiratory event motion sensing comprising sensing chest wall motion and abdominal motion associated with respiratory effort. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) that are based on chest wall and abdominal motion (figures 2a, 2b; column 13, lines 23-47), in order to accurately determine the type of disordered breathing the patient experiences. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and used a motion sensor configured to monitor chest wall and/or abdominal effort motions as that sensor, as taught by Brydon, in order to accurately classify the patient's disordered breathing.

Regarding claims 19 and 61, Cho discloses all the elements of the claimed invention, as disclosed above, except for the respiratory event motion sensing comprising distinguishing between respiratory and non-respiratory motion. Burnes

teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) that can distinguish between respiratory and non-respiratory motion (column 14, lines 33-45), in order to remove artifacts from the effort signal. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and used a motion sensor configured to distinguish between respiratory and non-respiratory motion, as taught by Brydon, in order to remove artifacts from the effort signal.

Regarding claims 23 and 58, Cho discloses all the elements of the claimed invention, as described above, except for classifying the disordered breathing event as obstructive if the motion associated with respiratory effort is equal to or above a motion threshold. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) where the breathing is classified as obstructive if the motion signals meet or exceed a particular threshold (column 18, lines 53-59; column 9, lines 11-21), since respiratory effort is characteristic of obstructive apnea events. It would have been obvious to one of ordinary skill in the art

at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and classified the disordered breathing event as obstructive if the sensed respiratory effort motions met or exceeded a threshold, as taught by Brydon, since respiratory effort is characteristic of obstructive apnea events.

Regarding claims 24 and 59, Cho discloses all the elements of the claimed invention, as disclosed above, except for classifying the disordered breathing event as a central disordered breathing event if motion associated with respiratory effort is below a particular threshold. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) where the disordered breathing is classified as central if a particular effort motion threshold is not met (column 19 line 54 to column 20 line 25), since a lack of effort is characteristic of central apnea events. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and classified the disordered breathing event as central if the sensed respiratory effort motions were below a threshold, as taught by Brydon, since a lack of effort is characteristic of central apnea events.

Regarding claim 60, Cho discloses all the elements of the claimed invention

7. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Burnes.

Cho discloses all the elements of the claimed invention, as described above, except for the motion sensor and/or breathing detector being wirelessly coupled to the processor. Burnes teaches an implantable disordered breathing detection system that utilizes both implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), where the external sensors may be wirelessly connected to the system's processor (paragraph [0034]), in order to obtain a more complete analysis of the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Cho with an external, wirelessly connected sensor, as taught by Burnes, in order to obtain a more complete analysis of the patient's condition.

Allowable Subject Matter

8. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of claim 25, including, *inter-alia*, classifying the disordered breathing event as mixed central and obstructive disordered breathing if the respiratory effort motion is equal to or above a certain threshold for a first portion of the event and below the threshold during a second portion of the event.

The prior art of record fails to anticipate or make obvious the method of claim 60, including, *inter-alia*, classifying a disordered breathing event as obstructive if a motion threshold is met or exceeded during a first portion of the event, and as central if the motion signal is below a motion threshold during a second portion of the event.

Brydon discloses that signals indicative of both central and obstructive events may be expressed simultaneously during mixed apnea events (column 20, lines 43-46), and that a disordered breathing event would be classified as obstructive if a motion threshold is met or exceeded and as central if the threshold is not met, but does not disclose classifying portions of a single event as either of the two.

Burton (US Patent Application Publication 2007/0032733) discloses a method of classifying mixed central and obstructive disordered breathing events as when periods of both effort and non-effort are present in the respiration signal (paragraph [0510]).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2005/0065447 to Lee, which discloses a similar invention.

US Patent Application Publication 2005/0107838 to Lovett, which discloses a similar invention.

US Patent Application Publication 2005/0085865 to Tehrani, which discloses a similar invention.

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US Patent Application Publication 2004/0176695 to Poezevara, which discloses a similar invention.

US Patent Application Publication 2004/0059240 to Cho, which discloses a similar invention.

US Patent 6964641 to Cho, which discloses a similar invention.

US Patent 5944680 to Christopherson, which discloses a similar invention.

US Patent 5522862 to Testerman, which discloses a similar invention.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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